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November 26, 2003

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1637**

Re: U.S. Utility Patent Application  
Appl. No. 09/891,332; Filed: June 27, 2001  
For: **Polymerases for Analyzing or Typing Polymorphic  
Nucleic Acid Fragments and Uses Thereof**  
Inventors: SOLUS *et al.*  
Our Ref: 0942.4250003/BJD/JKM

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Second Supplemental Information Disclosure Statement;
2. List of cited references on Form PTO-1449 (23 sheets);
3. A copy of each reference cited on Form PTO-1449 (80 documents: **AP3-AM6, and AS12-AS34**); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
November 26, 2003  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

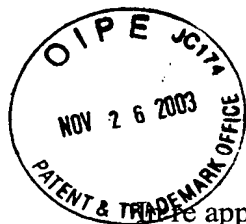
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono", written over a horizontal line.

Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

BJD/JKM/acr  
Enclosures

SKGF\_DC1:203813.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re application of:

SOLUS *et al.*

Appl. No. 09/891,332

Filed: June 27, 2001

For: **Polymerases for Analyzing or  
Typing Polymorphic Nucleic Acid  
Fragments and Uses Thereof**

Confirmation No. 4572

Art Unit: 1637

Examiner: Tung, J.

Atty. Docket: 0942.4250003/BJD/JKM

**Second Supplemental Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation in the numbering of Applicants' Information Disclosure Statement filed on October 5, 2001, and Applicants' First Supplemental Information Disclosure Statement filed electronically herewith, in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Payment of the fee under 37 C.F.R. § 1.17(p) is included with the First Supplemental Information Disclosure Statement filed electronically herewith. It is believed that this fee covers both submissions.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

Date: Nov. 26, 2003

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
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FORM PTO-1449  SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4250003/BJD/JKM	APPLICATION NO. 09/891,332
	APPLICANT SOLUS et al.	
	FILING DATE June 27, 2001	GROUP 1637

U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP3	EP 0 258 017 B1	03/02/1988	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR		
	AS	<u>12</u>	Astatke, M., et al., "Deoxynucleoside Triphosphate and Pyrophosphate Binding Sites in the Catalytically Competent Ternary Complex for the Polymerase Reaction Catalyzed by DNA Polymerase I (Klenow Fragment)," J. Biol. Chem. 270:1945-1954, The American Society for Biochemistry and Molecular Biology, Inc. (1995).
	AT	<u>12</u>	Barnes, W.M., "The fidelity of Taq polymerase catalyzing PCR is improved by an N-terminal deletion," Gene 112:29-35, Elsevier Science Publishers B.V. (1992).

EXAMINER	DATE CONSIDERED
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4	EP 0 351 138 B1	01/17/1990	Europe			Yes No
	AM4	WO 90/08839 A1	08/09/1990	WIPO			Yes No
	AN4	EP 0 386 859 B1	09/12/1990	Europe			Yes No
	AO4	WO 91/02090 A1	02/21/1991	WIPO			Yes No
	AP4	WO 91/16446 A1	10/31/1991	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>13</u>	Basu, A., and Modak, M.J., "Identification and Amino Acid Sequence of the Deoxynucleoside Triphosphate Binding Site in <i>Escherichia coli</i> DNA Polymerase I," <i>Biochemistry</i> 26:1704-1709, American Chemical Society (1987).	
AS	<u>13</u>	Beese, L.S., et al., "Crystal Structures of the Klenow Fragment of DNA Polymerase I Complexed with Deoxynucleoside Triphosphate and Pyrophosphate," <i>Biochemistry</i> 32:14095-14101, American Chemical Society (1993).	
AT	<u>13</u>	Bergquist, P.L., et al., "Genetics and Potential Biotechnological Applications of Thermophilic and Extremely Thermophilic Microorganisms," <i>Biotechnol. Genet. Eng. Rev.</i> 5:199-244, Intercept, Ltd. (1987).	

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL5	WO 92/03556 A1	03/05/1992	WIPO			Yes No
	AM5	WO 92/06200 A1	04/16/1992	WIPO			Yes No
	AN5	WO 92/06202 A1	04/16/1992	WIPO			Yes No
	AO5	EP 0 516 245 A1	12/02/1992	Europe			Yes No
	AP5	WO 93/02212 A1	02/04/1993	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>14</u>	Bernad, A., et al., "A Conserved 3'-5' Exonuclease Active Site in Prokaryotic and Eukaryotic DNA Polymerases," Cell 59:219-228, Cell Press (1989).
	AS	<u>14</u>	Blanco, L., et al., "Evidence favouring the hypothesis of a conserved 3'-5' exonuclease active site in DNA-dependent DNA polymerases," Gene 112:139-144, Elsevier Science Publishers B.V. (1992).
	AT	<u>14</u>	Braithwaite, D.K., and Ito, J., "Compilation, alignment, and phylogenetic relationships of DNA polymerases," Nucleic Acids Res. 21:787-802, Oxford University Press (1993).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL6	WO 96/38568 A1	12/05/1996	WIPO			Yes No
	AM6	EP 0 655 506 B1	05/31/1995	Europe			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>15</u>	Carroll, S.S., et al., "A Mutant of DNA Polymerase I (Klenow Fragment) with Reduced Fidelity," <i>Biochemistry</i> 30:804-813, American Chemical Society (1991).
	AS	<u>15</u>	Chien, A., et al., "Deoxyribonucleic Acid Polymerase from the Extreme Thermophile <i>Thermus aquaticus</i> ," <i>J. Bacteriol.</i> 127:1550-1557, American Society for Microbiology (1976).
	AT	<u>15</u>	Darzins, A., and Chakrabarty, A.M., "Cloning of Genes Controlling Alginate Biosynthesis from a Muroid Cystic Fibrosis Isolate of <i>Pseudomonas aeruginosa</i> ," <i>J. Bacteriol.</i> 159:9-18, American Society for Microbiology (1984).

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INFORMATION DISCLOSURE STATEMENT**ATTY. DOCKET NO.  
0942.4250003/BJD/JKMAPPLICATION NO.  
09/891,332APPLICANT  
SOLUS et al.FILING DATE  
June 27, 2001GROUP  
1637**U.S. PATENT DOCUMENTS**

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>16</u>	Das, S.K., and Fujimura, R.K., "Mechanism of T5-induced DNA Polymerase. I. Replication of Short Primer Templates," <i>J. Biol. Chem.</i> 252:8700-8707, The American Society for Biochemistry and Molecular Biology, Inc. (1977).
	AS	<u>16</u>	Das, S.K., and Fujimura, R.K., "Processiveness of DNA Polymerases: A Comparative Study Using a Simple Procedure," <i>J. Biol. Chem.</i> 254:1227-1232, The American Society for Biochemistry and Molecular Biology, Inc. (1979).
	AT	<u>16</u>	Delarue, M., et al., "An attempt to unify the structure of polymerases," <i>Protein Engin.</i> 3:461-467, Oxford University Press (1990).

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>17</u>	Derbyshire, V., et al., "Genetic and Crystallographic Studies of the 3',5'-Exonucleolytic Site of DNA Polymerase I," <i>Science</i> 240:199-201, American Association for the Advancement of Science (1988).
	AS	<u>17</u>	Derbyshire, V., et al., "The 3'-5' exonuclease of DNA polymerase I of <i>Escherichia coli</i> : contribution of each amino acid at active site to the reaction," <i>EMBO J.</i> 10:17-24, Oxford University Press (1991).
	AT	<u>17</u>	Donlin, M.J., and Johnson, K.A., "Mutants Affecting Nucleotide Recognition by T7 DNA Polymerase," <i>Biochemistry</i> 33:14908-14917, American Chemical Society (1994).

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	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>18</u>	Dunn, J.J., and Studier, F.W., "Complete Nucleotide Sequence of Bacteriophage T7 DNA and the Locations of T7 Genetic Elements," <i>J. Mol. Biol.</i> 166:477-535, Academic Press Inc. (London) Ltd. (1983).
	AS	<u>18</u>	Elie, C., et al., "Thermostable DNA polymerase from the archaebacterium <i>Sulfolobus acidocaldarius</i> : Purification, characterization and immunological properties," <i>Eur. J. Biochem.</i> 178:619-626, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1989).
	AT	<u>18</u>	Freemont, P.S., et al., "A Domain of the Klenow Fragment of <i>Escherichia coli</i> DNA Polymerase I Has Polymerase but No Exonuclease Activity," <i>Proteins: Struct. Funct. Genet.</i> 1:66-73, Alan R. Liss, Inc. (1986).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	19	Fujimura, R.K., and Roop, B.C., "Characterization of DNA Polymerase Induced by Bacteriophage T5 with DNA Containing Single Strand Breaks," <i>J. Biol. Chem.</i> 251:2168-2175, The American Society for Biochemistry and Molecular Biology, Inc. (1976).
	AS	19	Fujimura, R.K., et al., "Physical Locus of the DNA Polymerase Gene and Genetic Maps of Bacteriophage T5 Mutants," <i>J. Virol.</i> 53:495-500, American Society for Microbiology (1985).
	AT	19	Gerard, G.F., et al., "Poly(2'-O-methylcytidylate)·Oligodeoxyguanylate as a Template for the Ribonucleic Acid Directed Deoxyribonucleic Acid Polymerase in Ribonucleic Acid Tumor Virus Particles and a Specific Probe for the Ribonucleic Acid Directed Enzyme in Transformed Murine Cells," <i>Biochemistry</i> 13:1632-1641, American Chemical Society (1974).

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	AN						Yes No
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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	20	Gutman, P.D., and Minton, K.W, "Conserved sites in the 5'-3' exonuclease domain of <i>Escherichia coli</i> DNA polymerase," <i>Nucleic Acids Res.</i> 21:4406-4407, Oxford University Press (1993).
	AS	20	Huber, R., et al., " <i>Thermotoga maritima</i> sp. nov. represents a new genus of unique extremely thermophilic eubacteria growing up to 90°C," <i>Arch. Microbiol.</i> 144:324-333, Springer-Verlag (1986).
	AT	20	Huser, B.A., et al., "Isolation and characterisation of a novel extremely thermophilic, anaerobic, chemo-organotrophic eubacterium," <i>FEMS Microbiol. Lett.</i> 37:121-127, Elsevier (1986).

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FORM PTO-1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.4250003/BJD/JKM	APPLICATION NO. 09/891,332
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	AP						Yes No

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	AR	<u>21</u>	Ishino, Y., et al., "Amino Acid Sequence Motifs Essential to 3' - 5' Exonuclease Activity of <i>Escherichia coli</i> DNA Polymerase II," <i>J. Biol. Chem.</i> 269:14655-14660, The American Society for Biochemistry and Molecular Biology, Inc. (1994).
	AS	<u>21</u>	Ito, J., and Braithwaite, D.K., "Compilation and alignment of DNA polymerase sequences," <i>Nucleic Acids Res.</i> 19:4045-4057, Oxford University Press (1991).
	AT	<u>21</u>	Jannasch, H.W., et al., " <i>Thermotoga neapolitana</i> sp. nov. of the extremely thermophilic, eubacterial genus <i>Thermotoga</i> ," <i>Arch. Microbiol.</i> 150:103-104, Springer-Verlag (1988).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>22</u>	Joyce, C.M., et al., "Nucleotide Sequence of the <i>Escherichia coli</i> polA Gene and Primary Structure of DNA Polymerase I," <i>J. Biol. Chem.</i> 257:1958-1964, The American Society for Biochemistry and Molecular Biology, Inc. (1982).
	AS	<u>22</u>	Joyce, C.M., "Can DNA polymerase I (Klenow fragment) serve as a model for other polymerases?," <i>Curr. Opin. Struct. Biol.</i> 1:123-129, Current Biology, Ltd. (1991).
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	23	Kaboev, O.K., et al., "Purification and Properties of Deoxyribonucleic Acid Polymerase from <i>Bacillus stearothermophilus</i> ," <i>J. Bacteriol.</i> 145:21-26, American Society for Microbiology (1981).	
AS	23	Kaledin, A.S., et al., "Isolation and Properties of DNA Polymerase from Extremely Thermophilic Bacterium <i>Thermus aquaticus</i> YT1," <i>Biochem.</i> 45:494-501, Plenum Publishing Corporation (1980).	
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	AR	<u>24</u>	Klimczak, L.J., et al., "Purification and Characterization of DNA Polymerase from the Archaeobacterium <i>Methanobacterium thermoautotrophicum</i> ," <i>Biochemistry</i> 25:4850-4855, American Chemical Society (1986).
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	AT	<u>24</u>	Leavitt, M.C., and Ito, J., "T5 DNA polymerase: Structural-functional relationships to other DNA polymerases," <i>Proc. Natl. Acad. Sci. USA</i> 86:4465-4469, National Academy of Sciences (1989).

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	AR	<u>25</u>	Lin, T.-C., et al., "Cloning and expression of a T4 DNA polymerase," <i>Proc. Natl. Acad. Sci. USA</i> 84:7000-7004, National Academy of Sciences (1987).
	AS	<u>25</u>	Minkley, Jr., E.G., et al., "Escherichia coli DNA Polymerase I," <i>J. Biol. Chem.</i> 259:10386-10392, The American Society of Biological Chemists, Inc. (1984).
	AT	<u>25</u>	Modak, M.J., and Marcus, S.L., "Purification and Properties of Rauscher Leukemia Virus DNA Polymerase and Selective Inhibition of Mammalian Viral Reverse Transcriptase by Inorganic Phosphate," <i>J. Biol. Chem.</i> 252:11-19, The American Society for Biochemistry and Molecular Biology, Inc. (1977).

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	AR	<u>26</u>	Ollis, D.L., et al., "Structure of large fragment of <i>Escherichia coli</i> DNA polymerase I complexed with dTMP," <i>Nature</i> 313:762-766, Nature Publishing Group (1985).
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	AR	<u>27</u>	Polesky, A.H., et al., "Identification of Residues Critical for the Polymerase Activity of the Klenow Fragment of DNA Polymerase I from <i>Escherichia coli</i> ," <i>J. Biol. Chem.</i> 265:14579-14591, The American Society for Biochemistry and Molecular Biology, Inc. (1990).
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	AT	<u>27</u>	Prasad, V.R., et al., "Isolation and characterization of a dideoxyguanosine triphosphate-resistant mutant of human immunodeficiency virus reverse transcriptase," <i>Proc. Natl. Acad. Sci. USA</i> 88:11363-11367, National Academy of Sciences (1991).

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	AR	<u>28</u>	Reeve, M.A., and Fuller, C.W., "A novel thermostable polymerase for DNA sequencing," <i>Nature</i> 376:796-797, Nature Publishing Group (1995).
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	AR	29	Rossi, M., et al., "Structure and Properties of a Thermophilic and Thermostable DNA Polymerase Isolated from <i>Sulfolobus solfataricus</i> ," <i>System. Appl. Microbiol.</i> 7:337-341, Gustav Fischer Verlag (1986).
	AS	29	Sagner, G., et al., "Rapid filter assay for the detection of DNA polymerase activity: direct identification of the gene for the DNA polymerase from <i>Thermus aquaticus</i> ," <i>Gene</i> 97:119-123, Elsevier (1991).
	AT	29	Sawaya, M.R., et al., "Crystal Structure of Rat DNA Polymerase $\beta$ : Evidence for a Common Polymerase Mechanism," <i>Science</i> 264:1930-1935, American Association for the Advancement of Science (1994).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>30</u>	Shengyu, Y., and Guofan, H., "Heat-Stable DNA Polymerase I Large Fragment Resolves Hairpin Structure in DNA Sequencing," <i>Sci. Sin. (Series B)</i> 30:503-507, Academia Sinica (1987).
	AS	<u>30</u>	Simpson, H.D., et al., "Purification and some properties of a thermostable DNA polymerase from a <i>Thermotoga</i> species," <i>Biochem. Cell Biol.</i> 86:1292-1296, National Research Council of Canada (1990).
	AT	<u>30</u>	Slater, M.R., et al., "DNA Polymerase I of <i>Thermotoga neapolitana</i> (Tne) and Mutant Derivatives," Seventh International Genome Sequencing and Analysis Conference, <i>Genome Sci. Technol.</i> 1:47, Abstract No. A-33, Mary Ann Liebert, Inc. (1995).

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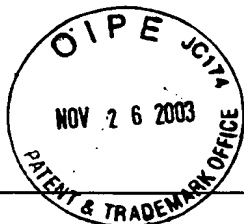
	AR	<u>31</u>	Song, Q., et al., "Mutagenesis of the Glu-89 Residue in Human Immunodeficiency Virus Type 1 (HIV-1) and HIV-2 Reverse Transcriptases: Effects on Nucleoside Analog Resistance," <i>J. Virol.</i> 66:7568-7571, The American Society for Microbiology (1992).
	AS	<u>31</u>	Sousa, R., et al., "Crystal structure of bacteriophage T7 RNA polymerase at 3.3 Å resolution," <i>Nature</i> 364:593-599, Nature Publishing Group (1993).
	AT	<u>31</u>	Spadari, S., and Weissbach, A., "HeLa Cell R-Deoxyribonucleic Acid Polymerases: Separation and Characterization of Two Enzymatic Activities," <i>J. Biol. Chem.</i> 249:5809-5815, The American Society for Biochemistry and Molecular Biology, Inc. (1974).

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AT	32	Tabor, S., et al., " <i>Escherichia coli</i> Thioredoxin Confers Processivity on the DNA Polymerase Activity of the Gene 5 Protein of Bacteriophage T7," <i>J. Biol. Chem.</i> 262:16212-16223, The American Society for Biochemistry and Molecular Biology, Inc. (1987).	

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	AR	<u>33</u>	Tabor, S., and Richardson, C.C., "Selective Inactivation of the Exonuclease Activity of Bacteriophage T7 DNA Polymerase by <i>in Vitro</i> Mutagenesis," <i>J. Biol. Chem.</i> 264:6447-6458, The American Society for Biochemistry and Molecular Biology, Inc. (1989).
	AS	<u>33</u>	Tabor, S., and Richardson, C.C., "A single residue in DNA polymerases of the <i>Escherichia coli</i> DNA polymerase I family is critical for distinguishing between deoxy- and dideoxyribonucleotides," <i>Proc. Natl. Acad. Sci. USA</i> 92:6339-6343, National Academy of Sciences (1995).
	AT	<u>33</u>	Tabor, S., and Richardson, C.C., "Effect of manganese ions on the incorporation of dideoxynucleotides by bacteriophage T7 DNA polymerase and <i>Escherichia coli</i> DNA polymerase I," <i>Proc. Natl. Acad. Sci. USA</i> 86:4076-4080, National Academy of Sciences (1989).

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	AR	<u>34</u>	Windberger, E., et al., "Thermotoga thermarum sp. nov. and Thermotoga neapolitana occurring in African continental solfataric springs," Arch. Microbiol. 151:506-512, Springer-Verlag (1989).
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